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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|---------------------|------------------|
| 09/700,057 | 02/05/2001 | Colin Brown | 9052-67 | 1282 |
| 20792 | 7590 | 03/25/2005 | EXAMINER | |
| MYERS BIGEL SIBLEY & SAJOVEC | | | WHITE, EVERETT NMN | |
| PO BOX 37428 | | | ART UNIT | PAPER NUMBER |
| RALEIGH, NC 27627 | | | 1623 | |

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/700,057 | BROWN, COLIN |
| | Examiner | Art Unit |
| | EVERETT WHITE | 1623 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 January 2005.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2,4-10,15-18,21-23,26-35 and 39-44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 23 and 26-35 is/are allowed.

6) Claim(s) 1,2,4-10,15-18,21,22 and 39-44 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 18, 2005 has been entered.
2. The amendment filed January 18, 2005 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claims 3, 11-14, 19, 20, 24, 25 and 36-38 have been canceled;
 - (B) New Claim 44 has been added;
 - (C) Claims 1, 4, 5, 15, 16, 23, 32-34 and 40 have been amended;
 - (D) Comments regarding Office Action have been provided drawn to:
 - (I) 112, 2nd paragraph rejection, which has been withdrawn;
 - (II) 102(b) rejection, which has been maintained for the reasons of record;
 - (III) 103(a) rejection over the Viegas et al patent in view of the Davies patents, which has been maintained for the reasons of record.
 - (IV) 103(a) rejection over the Viegas et al patent in view of the Milner patent, which has been withdrawn.
3. Claims 1, 2, 4-10, 14-18, 21-23, 26-35, and 39-43 are pending in the case.
4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, 2nd Paragraph

5. Claims 22, 39 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding **Claim 22**, in the absence of the specific analogue of prostacyclin, specific analogue of a fibrinolytic agent, and a specific analogue of an anti-inflammatory agent, analogues to the chemical core claimed (prostacyclin, fibrinolytic agent or anti-

Art Unit: 1623

inflammatory agent) or distinct language to describe the structural modifications or the chemical names of the analogues of this invention, the identity of said analogues would be difficult to describe and the metes and bounds of said analogues that Applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

Applicants are reminded that a difference in intended use cannot render a claimed composition novel. Note *In re Tuominen*, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161.

Claim 39, which is drawn to products containing an aqueous formulation of the polysaccharide dextrin of Claim 22, recites as a limitation "a combined preparation for use in reducing the incidence of adhesions in a body cavity", which is a recitation of intended use of the product of Claim 22. In the absence of further product limitation, the claim is seen to be a substantial duplicate, and said recitation is not afforded critical weight and fails to further limit the product of Claim 22, which **Claim 39** is dependent from. **Claim 39**, which is seen to be a substantial duplicate, should be canceled or amended to provide a tangible manipulative difference (further limitation) in the product of Claim 22.

The recitation of an intended use, chemical activity or functional description of some "additional" property for a product (or functionality associated to the product) used in a process for the product, must result in an actual further limitation to the product in order to be further limiting. In **Claim 44** the intended activity is seen to be "the solution remains a solution in the body cavity". In the absence of said further product limitation, the claim is seen to be a substantial duplicate, and said activity is not afforded critical weight and fails to further limit the product of Claim 2, from which **Claim 44** depends. **Claim 44**, which is seen to be a substantial duplicate, should be canceled or amended to provide a tangible manipulative difference (further limitation) in the product of Claim 2.

6. Applicant's arguments with respect to Claims 22, 39 and 44 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, and 4-10, 15 and 16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Davies (US Patent No. 5,258,175, already of record).

Applicant claims a composition comprising an aqueous formulation containing a polysaccharide dextrin in an amount effective to reduce adhesions in a body cavity, wherein the dextrin is unsubstituted and contains more than 15% of polymers with a degree of polymerization (DP) greater than 12, wherein the dextrin is present in a amount of from 2.5-18% weight to volume of the composition. Additional limitations in the dependent claims include the aqueous formulation being a solution, specifying the amount of 1,6 linkages in the dextrin, specifying the number average molecular weight and weight average molecular weight of the dextrin, and further specifying the amount of dextrin present in the composition,

The Davies patent discloses a dextrin used to prepare a dextrin derivative that is derived from a dextrin which is a glucose polymer mixture containing at least 15%, preferably at least 50%, by weight of glucose polymers of D.P. (degree of polymerization) greater than 12. Davies discloses the dextrin as having a weight average molecular weight of from 15,000 to 25,000 (see column 2, paragraphs 1 and 2), which fall within the weight average molecular weight range disclosed in instant Claims 8 and 9. See Example 1 wherein a solution starch dextrin in water is set forth, which anticipates a dextrin solution of the instant claims. Also see column 6, lines 59 and 60 wherein Example 11 discloses a solution containing 5% dextrin. Accordingly, the dextrin composition of the Davies patent anticipates the dextrin composition of the instant claims.

9. Applicant's arguments filed January 18, 2005 have been fully considered but they are not persuasive. Applicants amended Claim 1 to recite that the dextrin is present in

an amount of from 2.5-18% weight to volume of the composition. However, the amendment does not over come the rejection of the claims since the Davies patent discloses in Example 11 (see column 6, lines 59 and 60) a solution containing 5% dextrin, which anticipate the amended limitation of Claim 1. Applicants further presented arguments regarding the use of the claimed composition (reducing the incidence of adhesions in a body cavity). Applicants are reminded that a difference in intended use cannot render a claimed composition novel. Note *In re Tuominen*, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161. Accordingly, the rejection of Claims 1, 2, and 4-10, 15 and 16 under 35 U.S.C. 102(b) as being anticipated by the Davies patent is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

10. Claims 1, 2, 4-10, 15-18, 21, 22 and 39-44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al (US Patent No. 5,587,175) in view of Davies (US Patent No. 5,258,175) for the reasons set forth in the previously filed Office Actions.

11. Applicant's arguments filed January 18, 2005 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that the Viegas et al patent is directed toward a film-forming polymer. As pointed out by Applicants, before being form into a film-forming polymer, the product is in the form of an aqueous solution, which is the form used to reject the instant claims. Applicants argue that one of ordinary skill in the art would not be motivated to combine the Davies patent (directed to dextrin derivatives for use in paraquat poisoning) and the Viegas patent (directed to film-forming polymers) to arrive at the present invention. In response to Applicant's argument the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case,

in column 1, 2nd paragraph, the Davies patent discloses the dextrin being used as an osmotic agent. One would be motivated to combine the Viegas et al patent with the Davies patent since Viegas et al sets forth dextrin compositions that provide a physiologically acceptable vehicle having hypoosmotic, hyperosmotic, or isoosmotic characteristics. Applicants further argue that for similar reasons, the combination of the Viegas patent and the Davies patent does not teach or suggest the products or kits recited in Claims 39 and 40-43, respectively. This argument is not persuasive since Claim 39 does not further limit the product of Claim 22, from which Claim 39 depends. Hence, Claim 39 is a substantial duplicate of Claim 22 (See the rejection of Claim 39 under 35 U.S.C. 112, 2nd paragraph, set forth above). Claim 22 is rejected herewith. The kits contain the product of instant Claim 1 and rise or fall with the patentability of Claim 1. Accordingly, the rejection of the claims as being unpatentable over the Viegas et al patent in view of the Davies patent is maintained for the reasons of record.

Allowable Subject Matter

12. Claims 23 and 26-35 are allowed.

Reason for Allowance

13. The following is an examiner's statement of reasons for allowance: Applicants amended Claim 23 to set forth that the aqueous formulation comprises a polysaccharide dextrin which is in the form of a solution in the body cavity and remains in the body cavity for at least 2 days. The Viegas et al and Milner patents do not recite a length of time for the solution thereof to remain in the body cavity. Hence, the prior art of record does not teach or fairly suggest a method of reducing the incidence of adhesions in a body cavity, comprising introducing into the body cavity a composition comprising a polysaccharide dextrin in an amount effective to reduce the incidence of said adhesion, wherein the dextrin is unsubstituted and the dextrin contains more than 15% of polymers with a degree of polymerization (DP) greater than 12 and acts as an osmotic agent to maintain a volume of the aqueous formulation in the body cavity serving to separate tissues which otherwise may adhere to each other.

Art Unit: 1623

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Summary

14. Claims 1, 2, 4-10, 15-18, 21, 22 and 39-44 are rejected; Claims 23 and 26-35 are allowed.

Examiner's Telephone Number, Fax Number, and Other Information

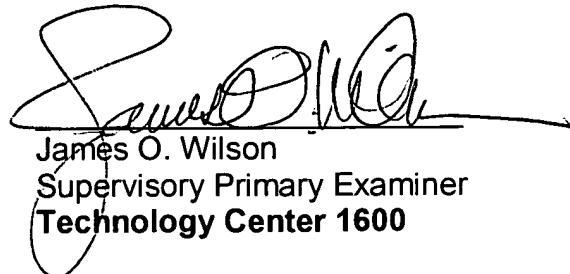
15. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


E. White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600